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10/727,779	12/03/2003	Shea N. Gardner	IL-11191	7079

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EXAMINER	
BERTAGNA, ANGELA MARIE	
ART UNIT	**PAPER NUMBER**
1637	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,779	GARDNER ET AL.	
	Examiner	Art Unit	
	Angela Bertagna	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) *1-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 12, 2007 has been entered.

Claims 1-11, 13, and 15-17 are currently pending. Claims 1-10 are withdrawn from consideration as being drawn to non-elected invention. In the response, claims 11, 13, and 15-17 were amended, and claim 14 was canceled.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of the prior-filed applications, Application No. 10/394,337 and Provisional Application No. 60/428,579, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, neither application provides support for the instant claims 15-17, because the earlier-filed applications do not teach that the length of the oligonucleotides starting thermocycle is computed by the formula: $l_c = n(c-1) + p_1$ for $c>1$ (claim 15), that the method is conducted using n-mers of a size n+1, n+2, etc (claim 16), and that the method is conducted using oligos in multiple reading frames (claim 17). Therefore, since the earlier-filed applications do not provide adequate support for the instant claims 15-17, the filing date of the instant application (December 3, 2003) has been used for prior art purposes.

Claim Interpretation

3. Claim 11, recites the new limitation "providing fragments of length n (n-mers) of a defined size....that correspond to said virtual fragments." "Corresponding" is not an art-recognized term to describe the relationship between two nucleic acid sequences, and the term has not been defined in the specification. For examination purposes, a pair of "corresponding" nucleic acids has been interpreted to include two nucleic acids with the same sequence, two nucleic acids that are complementary to one another, and two nucleic acids that share a region of sequence identity.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112, 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13, and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites "providing fragments of length n (n-mers)....that correspond to the virtual fragments" and "arraying ... fragments into groups." It is not clear whether these steps occur *in silico* or *in vitro*. More specifically, it is not clear whether the providing step intends to provide the fragments as part of the virtual breaking and subsequent temporal separation steps or if these fragments are provided for use in the *in vitro* reassembly steps. It is also not clear whether arraying step intends to purify/separate actual DNA fragments into groups (*e.g.*, into different tubes, parts of an array, *etc.*) or "virtually" array fragments by using a computer program. Since the relationship between the method steps is not clear, claims 11, 13, and 15-17 are indefinite. It is noted that if the providing and arraying steps are intended to recite *in vitro* steps, inclusion of the words "in vitro" in these steps would overcome the above rejection.

Claim 15 is further indefinite because not all of the terms appearing in the newly recited formula are defined in the claim. More specifically, the terms v_l and p_l are not defined.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans (US 2003/0087238 A1; cited previously). This pre-grant publication was filed August 2, 2001.

Regarding claim 11, Evans discloses a method of producing a DNA molecule of 1-10 kb of user-defined sequence (paragraph 53 teaches production of a 5 kb sequence) comprising:

(a) virtually pre-selecting a multiplicity of DNA segments that will comprise a user-defined DNA molecule by using computational techniques to virtually break the DNA molecule into fragments of length n, where n is an odd number (see Figure 3 and paragraphs 58 & 82)

(b) providing fragments of length n (n-mers) of defined size, where n is an odd number, that correspond to the virtual fragments (paragraphs 58 and 82)

(c) arraying the n-mers into groups (paragraphs 58 & 82 and Fig. 3)

(d) separating the n-mers temporally (paragraph 58 where Evans teaches sequential addition of the segments)

(e) assembling the groups into double-stranded DNA molecules of predetermined base-pairs using parallel synthesis, DNA shuffling, and DNA polymerase to produce the DNA

molecule of user-defined sequence (paragraphs 58 and 68 teach assembly using a polymerase; paragraphs 38 and 93-98 teach assembly by PCR, which inherently comprises parallel synthesis and shuffling using a DNA polymerase)

wherein the step of separating the DNA sequence segments occurs temporally (see paragraph 58) and the step of assembling the groups into double-stranded DNA molecules of pre-determined base pairs is accomplished by adding the DNA sequence segments gradually, in sequence order (paragraph 58).

Regarding claim 13, Evans teaches that the DNA segments are added gradually, in sequence order (paragraph 58). Evans further teaches that the sequential addition minimizes errors (paragraph 66) and that computational techniques may be use to optimize (i.e. minimize errors) in the entire method (paragraph 178). Evans further teaches that the resulting polynucleotide is 5 kb (paragraph 53), which anticipates the claimed size range of 1-10 kb.

7. Claims 15-17 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Evans (2003/0087238 A1; published May 8, 2003; filed August 2, 2001; cited previously). As noted above, claims 15-17 have not been granted benefit of the earlier filing date of the previously filed provisional and non-provisional applications, but rather the instant application filing date of December 3, 2003. Therefore, these claims are rejected under 102(a) and 102(e).

Regarding claim 15, Evans teaches that the oligonucleotides used to assemble the 1-10 kb DNA molecule have an overlap length (see paragraphs 52, 54, and 82). Evans does not teach that the length of the oligonucleotides starting a particular thermocycle is governed by the claimed formula: $l_c = n(c-1) + p_1$, where for $c>1$, $p_1 = n - v_1$. However, this formula inherently

governs the length of the oligonucleotides at each thermocycle used in the reassembly method of Evans, because the claimed formula is simply an empirical description of what inherently occurs when overlapping oligonucleotides with a specific overlap length are added in a sequential order and thermocycled in the presence of a DNA polymerase.

Regarding claim 16, Evans teaches that the oligonucleotides may be different lengths (paragraph 53). Evans further teaches examples of oligonucleotides with lengths of 15 (n), 16 (n+1), 17 (n+2), etc (see paragraph 53).

Regarding claim 17, Evans teaches that the multiplicity of DNA fragments comprises oligos in multiple reading frames. Specifically, Evans teaches variation of the oligo length and overlap between the fragments (paragraphs 53 and 54). These DNA fragments inherently comprise multiple reading frames.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 11, 13, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selifonov et al. (WO 00/42560; cited previously) in view of Evans (US 2003/0087238 A1; cited previously).

Selifonov discloses a method of making polynucleotides having user-defined characteristics (see for a general description, pages 3-6 "Summary of Invention" and also page 9, lines 23-31).

Regarding claim 11, Selifonov discloses a method of producing a DNA molecule of user-defined sequence comprising:

(a) virtually preselecting a multiplicity of DNA segments that will comprise a user-defined DNA molecule by using computational techniques to virtually break the DNA molecule into virtual fragments of length n (n-mers), where n is an odd number (page 14, lines 20-29 and page 21, lines 12-22 teach using computational methods to virtually break the DNA molecule into virtual fragments; page 6, lines 8-10 teach using n-mers where n is an odd number)

(b) providing fragments of length n (n-mers) of defined size, where n is an odd number, that correspond to the virtual fragments (page 9, lines 23-31 and page 21, lines 12-30 teach providing fragments *in vitro* that correspond to the virtual fragments generated in step (a) above; page 6, lines 8-10 teaches using n-mers where n is an odd number in the synthesis method)

(c) arraying the fragments of defined size into groups (page 14, lines 27-30, where Selifonov teaches that the fragments may be left with the parental strands or transferred to a new

population. Selifonov also teaches formation of new populations; see also page 21, lines 14-15 and lines 23-30, where sets are combined)

(d) separating the DNA sequence segments temporally (page 22, lines 4-19, where Selifonov teaches variation of the composition of fragments in the recombination reaction and/or performing multiple recombination reactions. This is a temporal separation of the DNA segments)

(e) assembling the groups into double-stranded DNA molecules of predetermined base-pairs using parallel synthesis, DNA shuffling, and DNA polymerase to produce the DNA molecule of user-defined sequence (page 21, line 23 – page 22, line 13).

See also Figures 4A-D for a flow-chart depiction of the method of Selifonov.

Further regarding claim 11, Selifonov teaches that the assembled polynucleotide of user-defined sequence is 1.6 kb (page 70), a value within the claimed range of 1-10 kb.

Regarding claim 15, Selifonov teaches that the oligonucleotides used to assemble the 1-10 kb DNA molecule have an overlap length (see page 21, lines 23-30, page 22, lines 12-18, and page 33, lines 1-7). Selifonov does not teach that the length of the oligonucleotides starting a particular thermocycle is governed by the claimed formula: $l_c = n(c-1) + p_l$, where for $c>1$, $p_l = n - v_l$. However, this formula inherently governs the length of the oligonucleotides at each thermocycle used in the reassembly method of Selifonov, because the claimed formula is simply an empirical description of what inherently occurs when overlapping oligonucleotides with a specific overlap length are added in a sequential order and thermocycled in the presence of a DNA polymerase

Regarding claim 17, Selifonov teaches that the multiplicity of DNA fragments comprises oligos in multiple reading frames. Specifically, Selifonov teaches variation of the oligo length and overlap between the fragments (page 33, lines 1-6). These DNA fragments inherently comprise multiple reading frames.

Regarding claims 11 and 13, Selifonov teaches computational modeling in an effort to minimize reassembly errors (see for example, page 10, lines 26-33). However, Selifonov does not explicitly teach sequential addition of DNA segments in the reassembly process.

Evans teaches a method of synthesizing a user-defined nucleic acid sequence that anticipates the instant claims 11, 13, and 15-17, as discussed above.

Regarding claims 11 and 13, Evans teaches that addition of the oligonucleotides in a sequential order (optimized by computational modeling) minimizes reassembly errors (see paragraphs 58, 66, and 178). Specifically, Evans stated, "The sequential polynucleotide assembly methods of the invention further reduce the error rate observed with methods that require hybridization of pools of large numbers of oligonucleotides" (paragraph 66). Evans further stated, "The sequential polynucleotide assembly methods of the invention eliminate the need for purification and allow for systematic assembly of identical sized double-stranded or single-stranded oligonucleotides" (paragraph 66).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize the *in silico*-optimized sequential addition of DNA fragments taught by Evans in the nucleic acid synthesis method of Selifonov. Evans expressly taught the advantages of sequential addition of oligonucleotide segments in sequence order, namely: (1) a reduction in the assembly error rate, (2) elimination of the need for an extra purification step and

(3) parallel synthesis of identical-sized nucleic acids (see paragraph 66 and above). An ordinary practitioner would have been motivated by these teachings of Evans to sequentially add the fragments to the reassembly reaction in sequence order in order to improve the accuracy of the reassembly reaction, eliminate the need for further purification (thereby improving the speed and efficiency of the process), and obtain the ability to synthesize in parallel multiple, identically-sized nucleic acids. Thus, the method of the instant claims 11, 13-15, and 17 is prima facie obvious over Selifonov in view of Evans.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Selifonov et al. (WO 00/42560; cited previously) in view of Evans (US 2003/0087238 A1; cited previously) and further in view of Murphy et al. (USPN 6,994,963; cited previously).

The combined teachings of Selifonov and Evans result in the method of claims 11, 13, 15, and 17, as discussed above.

Selifonov teaches variation of DNA segment lengths and the use of a set of DNA segments comprising fragments of different lengths (see page 6, lines 8-10 and page 33, lines 1-6). However, Selifonov does not explicitly teach fragments of n+1, n+2, etc.

Murphy teaches a method of nucleic acid recombination. Briefly, the method of Murphy comprises primer extension and cleavage to create an "extension ladder" (column 4, lines 9-16) followed by recombinatorial synthesis to produce a mutagenized or chimeric nucleic acid (column 6, lines 34-40).

Regarding claim 16, Murphy teaches that the "extension ladder" (a collection of DNA segments) may comprise sequences of different length, specifically, sequences different by one

nucleotide increments (i.e. n, n+1, n+2, etc) (see column 6, lines 49-56). Regarding the differently sized sequences, Murphy stated, "Furthermore, the present invention may use a complete library of nucleic acid extension products that differ in length by a single base. As a result, recombinatorial mutagenesis results in recombined sequences with potential crossover points at every single nucleotide in a nucleic acid sequence (column 3, line 66 – column 4, line 4)."

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to utilize DNA fragments differing by one nucleotide in length (n, n+1, n+2, etc) in the recombination method resulting from the combined teachings of Selifonov and Evans, since Murphy expressly taught that such a fragment pool resulted in "recombined sequences with potential crossover points at every single nucleotide in a nucleic acid sequence" (column 3, line 66 – column 4, line 4). An ordinary practitioner of the method resulting from the combined teachings of Selifonov and Evans would have been motivated by the teachings of Murphy to utilize the above length-diverse fragment pool in order to maximize the diversity of the resulting recombined/reassembled sequences, thereby improving the method's ability to generate nucleic acids encoding proteins with improved functional properties. Thus, the method of claim 16 is prima facie obvious in view of the combined teachings of Selifonov, Evans, and Murphy.

Response to Arguments

11. Regarding the rejection of claims 11 and 13-17 as indefinite, under 35 U.S.C. 112, 2nd paragraph, Applicant's arguments have been fully considered but were not found persuasive. Applicant argues that the claim amendments overcome the rejection under § 112, 2nd paragraph

(see pages 1-2 of the response). This argument was not found persuasive, because as discussed above, it remains unclear as to which steps of the method are conducted *in silico* and which steps are conducted *in vitro*. Accordingly, the rejection has been maintained.

Regarding the rejection of claims 11 and 13-17 under 35 U.S.C. 102 as anticipated by Evans, Applicant's arguments filed June 12, 2007 have been fully considered but they are not persuasive. Applicant argues that the reference does not teach all of the limitations of the claims as amended (see pages 2-5). It is noted that the arguments do not point out any specific deficiencies in the Evans reference. The arguments recite all of the limitations of the pending claims and then assert that Evans does not teach these limitations. No specific arguments are presented describing why Evans fails to teach the claimed limitations. Applicant's arguments were not found persuasive, because as discussed above, Evans teaches all of the limitations of the instant claims 11, 13, and 15-17. Applicants are referred to sections 5 and 6 above, which point to the specific portions of the Evans reference where the claimed limitations are found. Since Applicant's arguments were not found persuasive, the rejection has been maintained.

Regarding the rejection of claims 11 and 13-17 under 35 U.S.C. 103(a), Applicant's arguments have been fully considered but were not found persuasive. Applicant argues for each of the rejections that the references individually fail to show the method steps, combining the references would not produce the claimed invention, and a prima facie case has not been made (see pages 6-18). This argument is not persuasive because Applicants' arguments are drawn to the references individually and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375

(Fed. Cir. 1986). Additionally, with respect to Applicant's assertion that no prima facie case has been made, Applicants are referred the above sections 8 and 9 and also to the rejections found in the Office Action mailed on March 29, 2007. In sections 8-9 above and the previously mailed Office Action, the rejections specifically detail the parts of each reference that are relied on for a specific teaching, and each rejection details a motivation to combine each of the references. Applicants do not allege specific problems with the rejections, but rather, generically assert that a prima facie case has not been made. These arguments are therefore not persuasive. Since Applicant's arguments were not found persuasive, the rejections are maintained.

Conclusion

No claims are currently allowable.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Angela Bertagna
Art Unit 1637 AMB
August 27, 2007

amb

JEFFREY FREDMAN
PRIMARY EXAMINER
8/31/07